K032164

OCT 2 3 2003

Section C. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, this 510(k) Summary is provided:

Submitter: Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325

Contact: Gerda Resch, Regulatory Affairs; (818) 576-4198; gerda.resch@medtronic.com

Name Of Device: Medtronic MiniMed Diabetes Data Management System (DDMS), model 7333

Predicate Device: Medtronic MiniMed Solutions Pumps and Meter software, model 7311

DDMS is a network based software system residing on a computer server platform connected to the Internet. The system is designed to download patient data from Medtronic MiniMed insulin pumps and supported third-party blood glucose meters to the DDMS central database. The data contained in DDMS is accessible to users using a standard browser, i.e. Microsoft Internet Explorer, on a PC that is connected to the Internet. Communication devices and cables required to facilitate the interface with Medtronic MiniMed pumps are connected to the user's PC and device data is downloaded through the PC and transmitted directly over the Internet to the DDMS server. Glucose meter interface cables are connected similarly to the user's PC for downloading to DDMS. The system provides additional capability for manual on-screen data entry of other clinical parameters for downloading to DDMS.

Intended Use Of The Device: DDMS is intended for use by diabetic patients and their health care providers for access to reports based on patient data that is downloaded from the electronic memory of supported Medtronic MiniMed pump models and third-party blood glucose meters. Reports can also include data that is manually inputted by the user into the system. Reports generated by this software are designed for use as tools to assist with diabetes patient self-management, therapy optimization and clinical assessment. The purpose of this software is to provide useful reports for analysis of data trends and patterns that can be referenced for monitoring glycemic control, insulin usage, and observation of overall diabetes management.

Comparison Of The Technological Features Of The New Device And Predicate Device: The technological features of the new device do not differ significantly from the predicate device. The minor differences are that DDMS transfers data from Medtronic MiniMed pumps and supported third party meters via the Internet to a DDMS central database while the Medtronic MiniMed Solutions Pumps and Meter software stores all data on the hard drive of the user's personal computer.

7/11/03

Gerda Resch, RAC — Date
Manager, Regulatory Affairs
Medtronic MiniMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Ms. Gerda P. Resch
Manager, Regulatory Affairs
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325-1219

Re: K032164
Trade/Device Name: Diabetes Data Management System
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 10, 2003
Received: October 17, 2003

Dear Ms. Resch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: Medtronic MiniMed Diabetes Data Management System (DDMS), Model 7333

Indications For Use: The Medtronic MiniMed Diabetes Data Management System (DDMS) is a service intended to facilitate the review and analysis of information downloaded from Medtronic MiniMed insulin infusion pumps and compatible home glucose meters. Information downloaded to or entered into a PC is transmitted via the Internet to a Medtronic MiniMed database. DDMS includes numerous options for the analysis and display of this information. The displays and reports available in DDMS may be useful in identifying the impact of insulin delivery, daily activities and diet on glucose control.

Patricia Cucente

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032164

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** __X__
(Per 21 CFR 801.109)